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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,472	03/09/2001	Alan R. Brooks	015303-000510US	7251

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,472	BROOKS ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *7-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *09/11/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-29 are pending in the application.

Election/Restriction

[2] Applicants' election with traverse of Group I, claims 1-6, in the response to the restriction requirement filed September 15, 2003, is acknowledged.

[3] Applicants traverse the restriction requirement on the grounds that examination of the subject matter of the inventions of Groups I-VI would not place a substantially greater burden on the examiner. Applicant's argument is not found persuasive.

In the Office action mailed June 19, 2003, the examiner set forth the following inventions:

I. Claim(s) 1-6, drawn to an isolated nucleic acid, an expression cassette, and an isolated eukaryotic cell comprising said expression cassette, classified in class 435, subclass 325.

II. Claim(s) 7 and 8, drawn to an isolated protein, classified in class 530, subclass 350.

III. Claim(s) 9, drawn to an antibody, classified in class 530, subclass 387.9.

IV. Claim(s) 10-18, drawn to a method of modulating estrogen signaling, classified in class 435, subclass 6.

V. Claim(s) 19-26, drawn to a method of detecting the presence of estrogen signaling, classified in class 435, subclass 6.

VI. Claim(s) 27-29, drawn to a method of identifying a compound capable of acting as an estrogen receptor agonist or antagonist, classified in class 435, subclass 7.1.

MPEP § 803 states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. With the exception of Groups IV and V, all of the inventions have separate classification and clearly the inventions of Groups IV and V would require a different field of

search because each of the inventions of Groups IV and V recites different limitations that would require different patent and non-patent literature text searches. Thus, co-examination of the inventions of Groups I-VI would place a serious burden on the examiner.

[4] The requirement is still deemed proper and is therefore made FINAL.

[5] Claims 7-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Specification/Informalities

[6] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification is improper, *e.g.*, page 16, line 31 of the specification. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[7] The use of the trademark "GeneChip™" (page 25, lines 27 and 29) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to

prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[8] Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. Claims 1-6 are drawn to an isolated nucleic acid encoding an estrogen-regulated GTP-binding protein gamma-12 subunit protein comprising SEQ ID NO:1, an expression cassette comprising said nucleic acid and an eukaryotic cell comprising said expression cassette.

The claimed polynucleotides have no substantial utility as further experimentation is required to establish its "real world" use as explained in detail below. It is noted that the specification asserts the polypeptide of SEQ ID NO:1 (encoded by SEQ ID NO:2 and 3) functions as an estrogen-regulated GTP-binding protein gamma-12 subunit protein (page 5, lines 6-7 of the specification). While the specification indicates that expression of SEQ ID NO:1 is upregulated by estrogen specifically by the alpha estrogen receptor (page 58, lines 20-27), the specification acknowledges the functional divergence of Gγ12 proteins (page 58, line 5 of the specification) and proposes the hypothesis that G-protein coupled signaling could play a role in the cardio-protective effects of estrogen

(page 58, lines 5-7 of the specification). However, confirmation of this hypothesis would clearly require further experimentation. In this case, the specification fails to identify a specific benefit of the claimed nucleic acids in currently available form and thus fails to establish a "real world" use for the claimed nucleic acids. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson,* 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966).

Applicants disclose various asserted utilities for the claimed polynucleotides including "the production of Gγ12 protein, for diagnostic assays, for therapeutic applications, for Gγ12 specific probes, for assays for Gγ12 binding and/or modulating compounds, to identify and/or isolate Gγ12 homologs from other species" (page 21, lines 27-30 of the specification). However, addressing the uses of the claimed polynucleotides for diagnostic assays and for therapeutic applications, the specification fails to disclose any specific disorders or disease conditions that can be diagnosed, treated, or prevented using the claimed polynucleotides and fails to provide the biological significance and the necessary guidance for diagnosing, treating, or preventing any disorder or disease condition using the claimed polynucleotides. In the absence of such disclosure, one of ordinary skill in the art is left to determine which – if any - disorders can be diagnosed, treated, or prevented using the claimed polynucleotides and the specific materials and conditions necessary for such. The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536,

148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Here the specification fails to provide a specific benefit in currently available form for the claimed polynucleotide as the claimed polynucleotide is suitable only for additional research in order that one of ordinary skill in the art may determine the biological significance of the claimed polynucleotides.

Addressing the asserted uses of the claimed polynucleotides for the production of Gγ12 protein, for Gγ12 specific probes, for assays for Gγ12 binding and/or modulating compounds, and to identify and/or isolate Gγ12 homologs from other species, it is noted that none of these utilities is specific for the claimed nucleic acids and instead apply to the broad class of claimed nucleic acids. In other words, any polynucleotide can be used to express a protein to assay for compounds that bind or modulate protein activity and any polynucleotide can be used as a probe for itself or other homologous sequences. As such, the claimed polynucleotides have no specific utility.

For the reasons stated above, the claimed polynucleotide has no specific and substantial utility.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[9] Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[10] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application 60/188,460, filed March 10, 2000 is acknowledged. The sequences of SEQ ID NO:1-3 of the instant application are disclosed in provisional application number 60/188,460 as SEQ ID NO:1-3, respectively (see Figures 1-3 of 60/188,460). Applicant is granted the benefit of the earlier filing date of provisional application 60/188,460 to the extent this provisional application provides support for the claimed subject matter. Accordingly, the following rejection(s) have been made based on an effective filing date of March 10, 2000.

[11] Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Database GenBank Accession Number AA245064 (gi:1875799, March 1997).

Claim 1 is drawn to an isolated nucleic acid encoding an estrogen-regulated GTP-binding protein gamma-12 subunit protein comprising SEQ ID NO:1. Claim 2 limits the nucleic acid of claim 1 to being a nucleic acid from a mouse. Database GenBank Accession Number AA245064 teaches a nucleic acid isolated from a mouse encoding a polypeptide that is 100% identical to SEQ ID NO:1. Database GenBank Accession Number AA245064 teaches the encoded polypeptide is similar to G-Protein Gamma-12 subunit. This anticipates claims 1-2 as written.

[12] Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Database GenBank Accession Number AA738730 (gi:2775982, January 1998). Claims 1-2 are drawn to an isolated nucleic acid as described above. Database GenBank Accession Number AA738730 teaches a nucleic acid isolated from a mouse encoding a polypeptide that is 100% identical to SEQ ID NO:1. Database GenBank Accession Number AA738730 teaches the encoded polypeptide is similar to guanine nucleotide-binding protein gamma-12 subunit. This anticipates claims 1-2 as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[13] Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Database GenBank Accession Number AA245064 or Database GenBank Accession Number AA738730 in view of Ausubel et al. ("Current Protocols in Molecular Biology", John Wiley and Sons, Inc., 1995). Claim 5 is drawn to an expression cassette comprising the nucleic acid of claim 1 and claim 6 is drawn to an eukaryotic cell comprising said expression cassette.

Database GenBank Accession Numbers AA245064 and AA738730 disclose the nucleic acids and teachings as described above. Database GenBank Accession Numbers AA245064 and AA738730 do not teach an expression cassette comprising their respective nucleic acid or a eukaryotic cell comprising said expression cassette.

At the time of the invention, methods of manipulating nucleic acids for protein expression in a mammalian host were well known in the art. For example, Ausubel et al. teach protein expression is a powerful means to study protein structure and function (page 16.12.1, right column, top). Ausubel et al. provide a general overview of protein expression in mammalian cells, including an example of an expression vector for protein expression using COS cells (pages 16.13.1-16.13.7).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to insert the nucleic acid of Database GenBank Accession Number AA245064 or AA738730 into an expression vector, transform a mammalian host cell with said expression vector, and use said host cell to produce a polypeptide. One would have been motivated to produce a polypeptide using a host cell

transformed with an expression vector comprising the nucleic acid of Database GenBank Accession Number AA245064 or AA738730 in order to study the encoded protein structure and function as taught by Ausubel et al. One would have a reasonable expectation of success for inserting the nucleic acid of Database GenBank Accession Number AA245064 or AA738730 into an expression vector, transforming a eukaryotic host cell with said expression vector, and using said host cell to produce a polypeptide because of the results of Database GenBank Accession Number AA245064 or AA738730 and Ausubel et al. Therefore, claims 5-6, drawn to an expression cassette and a eukaryotic host cell comprising said expression cassette would have been obvious to one of ordinary skill in the art.

Conclusion

[14] Status of the claims:

- Claims 1-29 are pending.
- Claims 7-29 are withdrawn from further consideration.
- Claims 1-6 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

11-24-03
DAVID STEADMAN
PATENT EXAMINER